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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,514	04/25/2005	Christophe Galopin	102790-131 (30070 US/2)	7074
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PARFOMAK, ANDREW N. NORRIS MCLAUGHLIN & MARCUS PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
04/29/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/532,514

**Applicant(s)**

GALOPIN ET AL.

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

Applicants' arguments, filed January 5, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 - Obviousness**

Claims 1-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (WO 99/13734 already of record) in view of H&R (Frescolat Cooling Ingredients 1999).

#### **Applicant's Arguments**

Applicant argues H&R fail to remedy the deficiencies of Wolf because it only discloses two options for using Frescolat ML. No where does H&R disclose melting Frescolat ML first and then adding it to a solvent. Thus the reference teaches away from the instant invention. Further, Wolf does not suggest a combination of menthyl lactate

and menthol carboxamide. Wolf also teaches water as a solvent and menthol carboxamide is insoluble in water. The present invention provides compositions with higher amounts of menthyl lactate than what would be achieved with dissolving them in a solvent.

Examiner's Response

Although H&R discloses melting the menthyl lactate followed by adding to an emulsion, one of ordinary skill in the art would recognize that melting the menthyl lactate first before adding it to a composition or solvent is within the teaching of the reference. Furthermore, in KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to increase the concentration of a compound such as menthyl lactate when in a liquid state. Accordingly, it would have been obvious to have initially melted the menthyl lactate when mixing menthyl lactate with another cooling agent such as WS-3, to obtain the desired concentration of menthyl lactate in the final composition. Further, it appears that Applicant is asserting unexpected results in regards to the combination of menthyl lactate and menthol carboxamide. This does not appear to be the case because it has been reported in the art that mixing two cooling

agents, one of which is menthyl lactate and the other menthol, form eutectic mixtures<sup>1</sup>. Thus, it would not appear that mixing menthyl lactate with a cooling agent such as menthol carboxamide would lead to a more concentrate solution, is totally unexpected. Further Applicant does not appear to show that dissolving the menthyl lactate with menthol carboxamide in a solvent would result in lower concentrations of menthyl lactate than initially melting menthyl lactate followed by adding it to menthol carboxamide and a solvent. Applicant appears to only show that menthyl lactate precipitates out of solution when menthol carboxamide is not present.

In regard to the Wolf not suggesting the combination of menthyl lactate and menthol carboxamide, the reference teaches the cooling composition will be one or more physiological cooling agents. These include menthyl lactate, menthyl succinate, N-2,3-trimethyl-2-isopropyl butanamide, N-substituted p-menthane carboxamide and mixtures thereof. This is supported by Applicant's own admission on page 9, second paragraph, where it is stated that the reference suggests the combination of WS-3 and menthyl lactate. The reference also discloses making a solution of the cooling agents. This suggests the combination of menthyl lactate and N-substituted p-menthane carboxamide. The cooling agents may be made into a solution, which would encompass a composition consisting of menthyl lactate and menthol carboxamide. The reference also discloses solvents other than water, e.g. alcohols (page 25, line 13-16). In regard to claim 6, Wolf suggests the combination of menthyl lactate and menthol carboxamide, therefore when the two components are mixed together in a solution, menthyl lactate is

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<sup>1</sup> Su et al. (US 2004/0018954) see paragraph 0010. It also discloses melting menthyl lactate before

capable of having a higher concentration because based on the instant specification, it appears the concentration is dependent on it being in the presence of menthol carboxamide. In regard to the product claims 5, 7-11, 13 and 16-18, these claims read on a solution of menthyl lactate and menthol carboxamide dissolved in a solvent and not on how the compositions are made.

Claims 1-18 are rejected.

No claims allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612